

Cambridge University Press

978-1-107-08735-4 - Biodesign: The Process of Innovating Medical Technologies

Editors Paul G. Yock, Stefanos Zenios, Josh Makower, Todd J. Brinton, Uday N. Kumar and F. T. Jay Watkins

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BIODESIGN

The Process of Innovating Medical Technologies

A practical guide to the new era of global opportunity and value-based innovation in medical technology

This step-by-step guide to medical technology innovation, now in full color, has been rewritten to reflect recent trends of industry globalization and value-conscious health-care. Written by a team of medical, engineering, and business experts, the authors provide a comprehensive resource that leads students, researchers, and entrepreneurs through a proven process for the identification, invention, and implementation of new solutions.

- Nearly 70 case studies on innovative products from around the world explore successes and failures, provide practical advice, and enable readers to learn from real projects.
- “Getting Started” sections for each chapter encourage readers to take action and apply what they’ve learned to their own work.
- A collection of nearly 300 videos, created for the second edition of the book, expand upon critical concepts, demonstrate essential activities within the process, and bring the innovation experience to life.
- A wealth of additional material supports the book, including active links to external websites and resources, supplementary appendices, and timely updates.
- New to this edition, two opening sections highlight the importance of globalization and cost-effective healthcare in the medtech industry, themes which are carried throughout the book.

Readers can access videos and additional materials quickly, easily, and at the most relevant point in the text within the ebook, or on the companion website at ebiodesign.org, alongside instructor resources.

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“Biodesign is on the forward edge of one of the most exciting new frontiers of healthcare. This impressive and engaging work provides a thorough look at the innovation process. But this is certainly not just for the scientific innovators: it is a must-read for anyone in any aspect of healthcare today.”

Alex Gorsky, *Chairman and CEO, Johnson & Johnson*

“I can’t think of a more important place to turn creativity loose than in designing the future of healthcare. But it’s a complicated scene – and it’s easy to get lost in the maze of stakeholders, regulation, and financing. Biodesign lays out a clear and logical map to find and pursue opportunities for real innovation. One of the core messages in this new edition is that, by placing the need for affordability up front in design process, innovators can more explicitly create technologies that bring value to the healthcare system. This is design thinking at its best!”

David Kelley, *Founder, Hasso Plattner Institute of Design at Stanford University, Founder, IDEO*

“A must-to-read textbook for anyone in academia or industry, in any country, who wants to innovate and deliver value to patients and health systems around the world.”

Koji Nakao, *Chairman of Terumo and the Japanese Federation of Medical Device Associations*

“If you want to know how to come up with a both innovative and transformative technology in medicine, there isn’t a better resource than this book by Paul Yock and his colleagues at Biodesign. Over 13 years ago, the program at Stanford brought together trans-disciplinary innovators – engineers, physicians and business experts – to not only design their formidable program, but to teach all the rest of us how to do it.”

Eric J. Topol, *Director, Scripps Translational Science Institute*

“This book on biodesign will be invaluable for any inventor or entrepreneur. It contains very useful information on such critical areas as design principles, regulatory issues, clinical trial strategies, intellectual property, reimbursement strategies, and funding- and it backs them up with interesting real-life experiences and case studies”.

Robert Langer, *David H. Koch Institute Professor, MIT*

“This practical but comprehensive resource is keeping up with the rapid developments affecting medical device innovation. The authors draw on their own extensive experiences and insights, as well as diverse case studies, to present the full range of strategic and operational considerations to bring valuable new therapies to patients in the US and around the world.”

Mark McClellan, *Director, Health Care Innovation and Value Initiative, Brookings Institution*

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To innovators – past, present, and future – and the patients who inspire them ...

... and in tribute to Wallace H. Coulter, a pioneer in developing
affordable healthcare technologies with a global impact.

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Preface

There is no greater satisfaction than seeing a patient being helped by a technology that you've had a hand in creating. And thanks to continuing advances in science and technology, healthcare is more open for innovation than at any time in history.

Despite this promise, however, medical technology innovators face significant hurdles – especially in the new era of cost containment. If not managed skillfully, patents, regulatory approval, reimbursement, market dynamics, business models, competition, financing, clinical trials, technical feasibility, and team dynamics (just to name a few of many potential challenges) can all prevent even the best idea from reaching patient care.

So, where should you begin as an innovator? What process can you use to improve your chances of success? What lessons can you learn from the inventors, engineers, physicians, and entrepreneurs who have succeeded and failed in this endeavor before? This book delivers practical answers to these important questions.

Who should read it and why?

Biodesign: The Process of Innovating Medical Technologies provides a comprehensive roadmap for identifying, inventing, and implementing new medical devices, diagnostics, and other technologies intended to create value for healthcare stakeholders. It has been written to be approachable for engineering, medical, and business students at both the undergraduate and graduate level, yet comprehensive and sophisticated enough to satisfy the needs of experienced entrepreneurs and medtech executives. For instructors, it provides a proven approach for teaching medical technology innovation that begins pre-idea and extends through preparing for commercialization. It is ideally suited to support team-oriented, project-based learning experiences in academic and industry settings.

The text describes the biodesign innovation process, which we initially developed to support the biodesign innovation and fellowship programs at Stanford University. Over 13+ years, the process has been built and refined based on:

- Presentations and mentoring by more than 200 industry leaders who have participated in our training programs
- Our experience advising more than 150 project teams that have applied the process to their work
- Feedback from those who have learned the process through our executive education courses, as well as input and suggestions from students, fellows, instructors at other universities, and industry representatives using the first edition of the book
- Extensive field-based research

Our confidence that the process is effective is based on the results of the students and fellows trained at Stanford and through our university-based partnerships in India and Singapore. Already over 30 of these projects have been converted to externally funded companies that have raised an aggregate of over \$250 million. More importantly, even though these are young companies, over 250,000 patients have already been treated by the technologies invented by our trainees. We have also been encouraged by the positive feedback we received on the process following the release of the first edition of the text.

What's new and important in the second edition of the biodesign book?

We initially wrote the *Biodesign* book because there was no comprehensive text that described the complete innovation process with a focus on the medical technology sector. Many excellent books address entrepreneurship generally or pieces of the device development

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process, but our goal was (and is) to provide a definitive, comprehensive resource for the medtech community.

Since the first edition of *Biodesign* was published in 2010, however, the medical technology industry and, more broadly, the healthcare ecosystem has experienced tumultuous change. As healthcare costs escalate on an unsustainable trajectory, a high priority is being placed on medical technologies that deliver *value* – that is, good outcomes at an affordable cost. In parallel with these forces, the global medical technology landscape is evolving rapidly, with large-scale demand for improved healthcare and a new focus on frugal innovation for developing economies. In this changing environment, veteran medtech innovators may feel as though they are treading unfamiliar new ground, and aspiring inventors and entrepreneurs are faced with navigating an even more complex and challenging landscape.

Besides the need to update the text in response to these major environmental changes, we felt a personal imperative to create the second edition. Over the past several years we have learned more about how to teach the biodesign innovation process. We've had the chance to use the text with students, fellows, entrepreneurs, and executives, and gather feedback from instructors at other universities around the world who are using it in their courses. Through these interactions, we realized that there were messages that we could clarify and some that we should emphasize more strongly. As a result, we have revised the text substantially for the second edition to address three critical factors:

1. **Value orientation** – The healthcare industry has become increasingly competitive, with the primary customers of medical technologies – governments, private payers, provider groups, and patients – focusing intensely on the cost of medical technologies and related services. In this environment, it is more essential than ever for products and related services to demonstrate measurable value to their intended users. The second edition of *Biodesign* more explicitly recognizes the importance of value generation in healthcare and includes guidance to better address this imperative in all phases of our process. Be sure to

read the section “Focus on Value” in the pages that follow the preface for more context on value and how it is treated within the text.

2. **Going global** – The first edition of the text was largely US-centric, but in the second edition we devote significantly more attention to describing the changes in the process of medtech innovation resulting from the growing importance of markets, clinical opportunities, and sources of innovation outside of the United States. We focus on key strategic considerations for operating in a more global healthcare environment and share substantially more examples from medtech innovators working around the world. To dig more deeply into some key issues, we have added a section on “Global Perspectives,” in which we spotlight six regions that present interesting medtech opportunities.
3. **Better ways to teach and learn** – While the fundamental biodesign innovation process remains the same in the new version of the text, we have rewritten a number of sections to provide more focus and clarity; and we offer more examples and case material in areas that are best understood experientially. One important take-away is that our approach appeared too linear in the first edition, and we have made concerted effort to explain within the chapters when and why a more iterative method is necessary. We have also captured a number of important lessons in the “Process Insights” section that follows the preface. Readers will significantly increase their effectiveness if they take these key themes to heart and keep them in mind as they work through the chapters within each major section of the text.

Our core belief remains that innovation is both a process and a skill that can be learned. We hope that the new edition of *Biodesign* will help to better equip aspiring and experienced innovators alike to be successful in the dynamic medtech industry. Tumultuous changes notwithstanding, the dynamics of the emerging healthcare burden around the world demand continued innovation, and technology innovators will continue to be central to this mission.

How to maximize the benefit of this book: a user’s guide

The steps in the biodesign innovation process build on each other and, in this respect, it makes sense for readers to work their way through the text in chapter order. Taking this approach provides innovators with the most complete understanding of the biodesign innovation process and the most valuable overall learning experience. We have heard of many medtech innovators using the text as a roadmap for their projects, starting at the beginning and following the process to help drive their progress.

That said, each chapter is sufficiently robust to support alternate approaches to the content. For instance, instructors can pick and choose the chapters most relevant to their specific courses (e.g., some of the chapters in the Implement section may be a bit advanced for undergraduates, but they are ideally suited to graduate-

level innovation or business planning classes). And experienced device executive and entrepreneurs can use the book as a reference as they encounter specific challenges on their way to market with a new technology.

In terms of organization, we present the biodesign innovation process in:

- three distinct **phases**, Identify, Invent, and Implement;
- that are divided into two **stages** each (six in total);
- which are supported by 29 core **activities**, with a chapter on each one.

Figure P1 summarizes the overall process. Keep in mind that it’s not nearly as linear in practice as it appears in this depiction. The iterative and cyclical nature of the process is further explained throughout the text.

As you navigate *Biodesign*, we encourage you to pay attention to a series of different features that

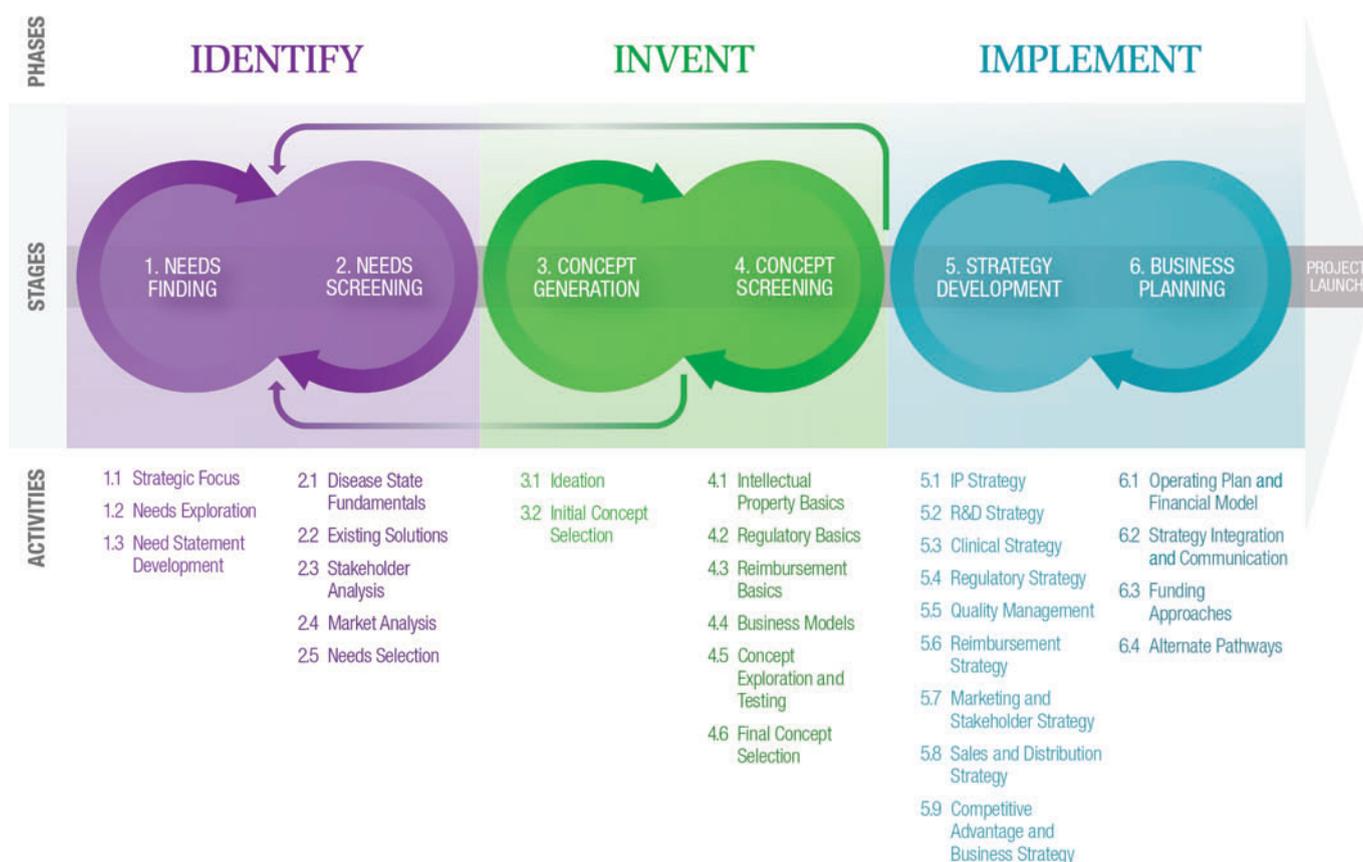


FIGURE P1
The biodesign innovation process.

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have been designed to help you optimize the value you receive from the text.

As you begin – Immediately following the preface, you’ll find relevant information that expands upon the three primary reasons we created the second edition of the book. These materials set a context for understanding and applying the content of the chapters.

- **Focus on value** – The medtech industry is in the midst of a transition to a stronger value orientation, in which the improvement a technology offers relative to its price is an essential ingredient of success. This section explores the forces behind this shift and their implications to innovators as they design, develop, and prepare to commercialize new products and services.
- **Global perspectives** – An introduction to factors driving the globalization of the medtech industry and changes in how innovators source, develop, and sell their technologies. We also profile six regions, Africa, China, Europe, India, Japan, and Latin America, providing background on these geographies, highlighting potential barriers to medtech innovation, and outlining tactics that can help innovators work more successfully in these areas.
- **Process insights** – Through feedback and our teaching experience, we have identified a series of key themes that you should keep top-of-mind while reading the chapters within each major section of the book. These are core strategies that cut across the stages and activities within each phase and will help you to keep on track as you proceed with the process. Instructors that emphasize these points in their teaching and readers who embrace this information will be able to navigate the biodesign innovation process more effectively.

Throughout the book – You should also be on the lookout for a few categories of information that have been added or broadened in the second edition.

New

- **Videos** – The second edition of *Biodesign* is supported by a brand new collection of nearly 300 videos on

topics spanning the complete biodesign innovation process. These clips, which include expert presentations and advice, interviews with innovators, demonstrations, and other exercises, are available to all readers in the video library at ebiodesign.org. Those reading the electronic version will find select videos embedded in the book directly where they are most relevant.

Expanded

- **“From the Field” case studies** – These short stories, which provide real-world examples of how innovators, teams, and companies have tackled important challenges in the biodesign innovation process, were one of the most popular features of the first edition. Accordingly, we increased the number of case studies by more than 50 percent. Look for 36 new and/or rewritten stories in the second edition of the text, many of which spotlight groups developing innovative medtech solutions outside of the US. At the end of each stage, we present a case study on Acclarent, maker of a device to treat chronic sinusitis. This running example spotlights how one real company executed the entire biodesign innovation process, from need finding to commercialization.

Updated

- **“Getting Started” sections** – For each chapter, readers will find a practical, action-oriented guide that they can follow to execute every step in the biodesign innovation process when working on an actual project. To make these sections more useful in the electronic version of the text, they have been populated with active web links to take readers directly to essential references and resources. In the print version, the key steps for getting started are listed, with the complete, interactive guides accessible at ebiodesign.org.

Enhanced

- **ebiodesign.org** – To better support the second edition of *Biodesign*, we have completely redesigned

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ebiodesign.org to be more user friendly and content rich. In addition to the video library and interactive getting started sections, ebiodesign.org includes additional content in the form of online appendices for many chapters. This is also where we'll post

important updates, new videos, and other learning materials as they become available. Instructors can access our course syllabus, select presentation slides, and exam questions/answers via the Instructor Resources section of the site.